REMARKS

In view of the amendments and remarks presented herein, Applicants request withdrawal of the rejections and favorable reconsideration of the claims.

I. Status of the Claims

Claims 1-12 are under consideration in the instant application. These claims were subject to a restriction requirement, in response to which, Applicants elected, with traverse, to prosecute the claims of Group I (*i.e.*, claims 1-5, 7 and 8). The restriction requirement was made final and hence claims 6 and 9-49 were withdrawn from consideration. These claims have been cancelled in the above amendment.

Claims 1-3, 5, 7 and 8 stand rejected under 35 U.S.C. §112, first paragraph and 35 U.S.C. §112, second paragraph, and claim 4 is objected to as being dependent from rejected claim 1. Applicants have amended claims 1, 2 and 3 to comport with the Written Description Guidelines and believe these amendments overcome the rejections of all of the claims. Applicants respectfully request that the rejections be reconsidered in light of the above amendments and the following remarks, and provide the following remarks for the Examiner's consideration. Applicants respectfully request reconsideration of the rejections in view of this response.

II. Rejection under 35 U.S.C. §112, second paragraph should be withdrawn

The rejection of Claim 7 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention, was maintained. Briefly reiterating the rejection, claim 7 was rejected for reciting the term "stringent" conditions, because this limitation renders the scope of the claim unclear. While Applicants maintain that one of skill in the art would understand the scope intended to be covered by this claim, Applicants have amended claim 7 to recite specific hybridization conditions which provide that hybridization be conducted at 42°C in a hybridization solution comprising 50% formamide, 1% SDS, 1 M NaCl, 10%

Dextran sulfate, and washing twice for 30 minutes at 60°C in a wash solution comprising 0.1x SSC and 1% SDS. This amendment is supported by the disclosure of the specification at page 27, lines 5-9. Applicants believe this amendment overcomes the remaining rejections of this claim and request that the claim be reconsidered for allowance.

III. Rejection under 35 U.S.C. §112, first paragraph for lack of written description should be withdrawn

The Office action indicates that claims 1-3, 5, 7 and 8 remain rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in such a way as to reasonably convey to one of skill in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection in view of the amendments presented herein above.

The claims were previously amended to such that each of the polypeptides of the claimed genus comprised a QACXG domain, had a catalytic function and were homologous to a specified sequence. The claims also had lower limits to the size of the proteins being claimed, *e.g.*, 30 contiguous amino acids in claim 1, 20 contiguous amino acids in claim 2 and 40 contiguous amino acids in claim 3. Applicants believe and previously pointed out that the format of these claims as previously amended comports with the suggested format in Example 14 of the written description guidelines. However, in the current Office action, the Examiner indicated that those arguments were not persuasive because while Applicants may have "provided for identifying at least [98%] identical variants of SEQ ID NO:77, that are capable of caspase activity, however, it remains to be seen if applicants have provided for identifying those variants that are merely 98% identical to any 30 contiguous amino acids of SEQ ID NO:77." (Office action, page 8).

In maintaining the rejection the Examiner directed Applicants to again review Example 14 of the Written Description Guidelines, stating that "the referred to claim is drawn to variants of SEQ ID NO:3 that are 95% identical to SEQ ID NO:3, not 98% identical to a fragment of SEQ ID NO:3." (Office action, page 8). As such, Applicants surmise that the

Examiner is taking issue with the 20, 30 and 40 amino acid long fragments encompassed by claims 2, 1 and 3 of the instant application. While Applicants maintain that the specification provides a written description of the genus of polypeptides that have at least 20 contiguous amino acids in length ***and*** contain a QACXG domain and a caspase catalytic activity. Applicants have amended the claim 1 to now recite:

> A purified and isolated caspase polypeptide comprising an amino acid sequence that is at least about 98% identical to an amino acid sequence set forth in SEQ ID NO: 77, wherein said polypeptide comprises a QACXG domain and possesses caspase activity.

Similar amendments have been affected in claims 2 and 3 (such that these claims refer to 95% and 90% homology respectively). With these amendments, Applicants believe the claims identify the percentage homology (98%, 95% and 90% for claims 1, 2 and 3 respectively), these claims also provide that the proteins being claimed must possess a given catalytic activity and that the proteins must possess a specific catalytic cysteine residue. Applicants submit that the claims as presently amended now mirror Example 14 of the Guidelines and request that the rejections of these claims be withdrawn. Claims 5, 7 and 8 ultimately depend from claims 1 and/or 2 and were rejected in part based on the fact that these claims depend on rejected independent claims. As the written description rejection of the independent claims is overcome, so is the rejection of these dependent claims. As such, Applicants respectfully request withdrawal of the rejection under §112, first paragraph, and reconsideration of the claims for allowance.

IV. Rejection under 35 U.S.C. §112 first paragraph for lack of enablement, should be withdrawn

Claims -3, 5, 7 and 8 were rejected under 35 U.S.C. §112, first paragraph because, according to the Examiner, while the specification is enabling for a caspase polypeptide comprising the amino acid sequence of SEQ ID NO:79 (for clarification of the record, Applicants point out that the sequence recited in the claims is SEQ ID NO:77, and the Examiner appears to have mis-transcribed the sequence as SEQ ID NO:79) , the specification

allegedly does not provide enablement for any caspase polypeptide comprising an amino acid sequence being at least 98% identical to 30 contiguous amino acids of SEQ ID NO:[77]. Applicants respectfully request reconsideration of the rejection in view of the amendments and remarks presented herein.

In maintaining the rejection of the claims of the invention, the Examiner states that the claims of the invention are not enabled, the Examiner states that "while routine experimentation is not undue, excessive routine experiment is undue" and as such the Examiner indicated that the genus of caspase polypeptides which encompasses any caspase comprising 98% identity to any 30 contiguous amino acids of the 373 amino acid sequence of SEQ ID NO:77 and the QACGX sequence is not enabled. (see Office action, page 10). Applicants have amended the claims to recite that caspases encompassed by the claims are 98%, 95%, and 90% homologous to a sequence of SEQ ID NO:77, possess caspase activity and further contain the QACGX sequence. Applicants believe this amendment obviates all of the rejections based on 35 U.S.C. §112, first paragraph for lack of enablement.

V. Conclusions

Applicants believe that all of the rejections have been overcome and the claims of the instant application are now in condition for allowance and request an early indication of such a favorable disposition of the case. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the referenced patent application.

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Respectfully submitted,

By _____

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